

VIRUSES, SERUMS, AND TOXINS FOR
TREATMENT OF DOMESTIC ANIMALS**§ 12.17 Importation restricted.**

The importation into the United States of viruses, serums, toxins, and analogous products for use in the treatment of domestic animals is prohibited unless the importer holds a permit from the Department of Agriculture covering the specific product. The port director shall notify the Animal and Plant Health Inspection Service, Veterinary Services, Washington, D.C., of the arrival of any such product, and detain it until he shall receive notice from that Department that a permit to import the shipment has been issued.

[28 FR 14710, Dec. 31, 1963, as amended by T.D. 78-99, 43 FR 13060, Mar. 29, 1978; T.D. 82-145, 47 FR 35476, Aug. 16, 1982; T.D. 89-1, 53 FR 51253, Dec. 21, 1988]

§ 12.18 Labels.

Each separate container of such virus, serum, toxin, or analogous product imported is required by the regulations of the Department of Agriculture to bear the true name of the product and the permit number assigned by the Department of Agriculture in the following form: "U.S. Veterinary Permit No. _____," or an abbreviation thereof authorized by the Animal and Plant Health Inspection Service, Veterinary Services. Each separate container also shall bear a serial number affixed by the manufacturer for identification of the product with the records of preparation thereof, together with a return date.

[28 FR 14710, Dec. 31, 1963, as amended by T.D. 78-99, 43 FR 13060, Mar. 29, 1978]

§ 12.19 Detention; samples.

(a) The port director shall detain all shipments of such products for which no permit to import has been issued pending instructions from the Department of Agriculture.

(b) Samples shall be furnished to the Department of Agriculture upon its request, and the port director shall immediately notify the consignee of any such request.

§ 12.20 Disposition.

Viruses, serums, or toxins rejected by the Department of Agriculture shall be released by the port director to that Department for destruction, or exported under Customs supervision at the expense of the importer if exportation is authorized by the Department of Agriculture.

VIRUSES, SERUMS, TOXINS, ANTITOXINS,
AND ANALOGOUS PRODUCTS FOR THE
TREATMENT OF MAN**§ 12.21 Licensed establishments.**

The bringing into the United States for sale, barter, or exchange, of any virus, therapeutic serum, toxin, antitoxin, or analogous product, or arspenamine or its derivatives (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of diseases or injuries of man is prohibited unless such virus, serum, toxin, antitoxin, or other product has been manufactured at an establishment holding an unsuspended and unrevoked license issued by the Secretary of Health and Human Services for such manufacture.

[T.D. 69-201, 34 FR 14328, Sept. 12, 1969, as amended by T.D. 82-145, 47 FR 35476, Aug. 16, 1982]

§ 12.22 Labels; samples.

Each package of such products imported for sale, barter, or exchange shall be labeled or plainly marked with the name, address, and license number of the manufacturer, and the date beyond which the contents cannot be expected to yield their specific results. From each lot of product the port director shall select at random at least two final containers. The random sample together with a copy of the associated documents which describe and identify the shipment shall be forwarded to the Director, Bureau of Biologics, Food and Drug Administration, 8800 Rockville Pike, Bethesda, Md. 20014. For shipments of 20 or less final containers, samples need not be forwarded, provided a copy of an official